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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|----------------------------|----------------------|---------------------|------------------|
| 10/581,692 | 06/06/2006 | Michael Boyd | MC098YP | 6637 |
| 210 MERCK AND | 7590 09/29/200 CO., INC | EXAMINER | | |
| PO BOX 2000 | | KOSACK, JOSEPH R | | |
| RAHWAY, NJ 07065-0907 | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/29/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/581,692 | BOYD ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Joseph R. Kosack | 1626 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| | / IO OFT TO EVEIDE & MONTH! | 0) OD THIDTY (00) BAYO | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period value or Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>05 A</u> | ugust 2009. | | | | | |
| | action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 53 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-5,7-9 and 11</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-5,7-9 and 11</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correct | | , , | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | | | | |
| Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal P 6) Other: | акті Аррікакон | | | | |

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DETAILED ACTION

Claims 1-5, 7-9, and 11 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2009 has been entered.

Previous Claim Rejections - 35 USC § 103

Claims 1-7, 9, and 11 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Bayly et al. (CA 2477657 and WO 03/075836, which correspond to the same document).

Claims 1-9 and 11 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Bayly et al. (CA 2477657 and WO 03/075836, which correspond to the same document).

The rejections have been reconsidered in light of the declaration of Dr. Cameron Black and the arguments submitted by the Applicant. The rejections are withdrawn because the Applicant has shown that the X group linker leads to an unexpectedly higher activity.

Previous Double Patenting Rejections

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Claims 1-9 and 11 were previously provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 1 and 25 of copending Application No. 12/082,104, now published as US PGPUB 2008/0188529.

The Applicant has requested that the rejection be held in abeyance. The policy of the U.S. Patent and Trademark Office is to make all applicable rejections at the start of prosecution to allow for compact prosecution. A rejection may not be held in abeyance for the sole reason that allowable subject matter has not yet been identified. Therefore, the rejection is maintained, except for claim 6, which has been cancelled.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-5, 7-9 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 1 and 25 of copending Application No. 12/082,104, now published as US PGPUB 2008/0188529. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same art specific subject matter.

'104 teaches a compound of the formula

corresponds to the compounds such as the elected species where R1 and R2 combine to form a C3 cycloalkyl, R3 is C4 alkyl subustituted with 1 halo, R4 and R5 are hydrogen, R6 is C1 alkyl substituted with two halo, n is 3, the first D is phenyl, the second D is phenyl, the third D is C3 cycloalkyl, R7 is C(O)N(R12)(R12), and each R12 is hydrogen. '104 also teaches the pharmaceutical composition and that the compound can be administered with an agent such as an organic bisphosphonate, an estrogen receptor modulator, an androgen receptor modulator, etc...

'104 does not specifically any of the species of the instant claim 8.

While '104 does not teach specifically a compound that falls within the species of claim 8, '104 understands that these compounds are a possibility from the detail of the generic formula. '104 provides numerous examples of compounds of the general formula that are useful as capthepsin inhibitors. Additionally, '104 does not provide any evidence of teaching away from the instant compounds. Hence, '104 invites the person of ordinary skill to generate other compounds of the genus with a reasonable

expectation of success that the compounds generated would also act as capthepsin inhibitors.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-5, 7-9, and 11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Joseph R Kosack/ Examiner, Art Unit 1626